**UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TENNESSEE**
**WESTERN DIVISION**

ONE STOCKDUQ HOLDINGS, LLC,

Plaintiff,

v.

BECTON, DICKINSON AND COMPANY,

Defendant.

Case No. 2:12-cv-03037-JPM-tmp

**JURY TRIAL DEMANDED**

# BECTON, DICKINSON AND COMPANY'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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## I. INTRODUCTION[1]

The defendant, Becton, Dickinson and Company ("BD"), submits this memorandum in response to the claim construction brief filed by the plaintiff, One StockDuq Holdings, LLC ("One-SD").

In addition, on October 1, 2013, the United States Patent and Trademark Office ("PTO") decided to institute an *inter partes* review ("IPR") of U.S. Patent No. 5,704,914 (the "'914 patent"), in response to BD's petition. (Halijan Decl. Ex. 1.) As part of that decision, the PTO offered the "broadest reasonable construction" for three claim terms: "flexible catheter,"[2] "flexible resilient diaphragm," and "between." (Halijan Decl. Ex. 1 at 8-13.) In this memorandum, the PTO's claim constructions are discussed along with the parties' proposed constructions.

## II. CLAIM TEXT TO BE INTERPRETED

One-SD insists that the Court construe large blocks of claim text that include numerous structural and functional limitations instead of discrete claim terms.

For example, One-SD proposes that the Court construe the following text from claim 31:

> flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub[.]

A dozen or more limitations on claim scope reside within this text. By asking the Court to construe the entire text at once, One-SD is seeking to rewrite the claim in a manner that ignores

[1] All exhibits referenced herein are attached to the Declaration of Douglas F. Halijan in Support of Defendant Becton, Dickinson and Company's Responsive Claim Construction Brief ("Halijan Decl."), filed concurrently herewith.

[2] Neither BD nor One-SD has proposed the term "flexible catheter" for construction in this case.

key limitations or substitutes new and unclear language that itself requires interpretation. Innumerable court cases interpret single words or short phrases of claim text in order to isolate and resolve the parties' disputes in a manner that will allow the Court or jury to properly decide the issues of infringement or validity. In the IPR decision on institution on the '914 patent, the PTO has construed the claims consistent with this accepted approach. This Court should do likewise.[3]

## III. CONSTRUCTION OF DISPUTED TERMS

### A. "Needle Attachment Body" (claims 22 and 31)

One-SD proposes that this term be construed as "housing that shields the tip of the needle when the needle is in the retracted storage position." This proposed construction is flawed in at least two respects. *First*, One-SD's proposed construction glaringly omits the concept of "needle attachment" from the claim term "needle attachment body." The explicit language of claims 22 and 31 require "a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an *opposite end attached to said body*." '914 patent, col. 11:32-34, col. 12:25-27 (emphasis added). Consequently, a construction for the term "needle attachment body" must address the *attachment* of the needle to the body.

*Second*, One-SD's construction that the "needle attachment body" "shield[s] the tip of the needle" introduces a functional requirement to the claim that has no support in the specification. (Br. at 7-8.) The '914 patent describes a body that houses the *entire* needle. *See* '914 patent, col. 3:67-4:11 (stating that the needle attachment body "provides a protective housing for the safe storage of *the needle*" when the needle is "recessed entirely" into the body (emphasis added)); *id.*

[3] As the Court is aware, BD and One-SD were unable to agree on what terms the Court should construe. Despite BD's attempt to engage One-SD in a discussion of this disagreement that might have simplified the issues before the Court, One-SD declined to discuss the parties' claim terms, waiting until it exchanged final claim constructions with BD to inform BD of its refusal to negotiate. (*See* Halijan Decl. Exs. 2 and 3.)

at col. 7:54-57 (stating that the needle attachment body "functions as a secure *needle containment unit*." (emphasis added)); *id*. at col. 8:23-26 (stating the needle attachment body "is also provided wherein the *needle* can be safely housed." (emphasis added)). Every embodiment in the '914 patent depicts a "needle attachment body" that fully houses the entire needle when the needle is retracted. *See, e.g., id.* at Fig. 3. Nowhere in the '914 patent is there any description of a structure that shields *only* the tip of the needle, as One-SD's construction suggests. In contrast, BD's construction provides for shielding "*the needle* after it is retracted" and is consistent with the '914 patent specification.

**B. "Connected to Said Hub" (claims 22 and 31)**

One-SD's proposed construction of "connected to said hub" (*i.e.*, "joined or linked to the hub") is inconsistent with the Federal Circuit's clear approach to claim construction. Rather than looking to the claims, specification, and prosecution history to support its construction, *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1318-19 (Fed. Cir. 2005) (*en banc*), One-SD relies *exclusively* on extrinsic evidence—a general dictionary—to support its construction. (Br. at 8.) Indeed, One-SD approaches claim construction backwards; looking first to extrinsic evidence to support its construction and only then turning to the '914 patent itself and concluding that "[n]othing in the prosecution history or specification conflicts with" One-SD's construction of the term "connected" as "joined or linked." (Br. at 8.) *See Phillips*, 415 F.3d at 1319 ("extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence"); *see also Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 832 (Fed. Cir. 2003) ("[r]esort to extrinsic evidence is appropriate only when an ambiguity remains after consulting the intrinsic evidence of record."); *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001) ("in the rare circumstance that the court is unable to determine the meaning of the asserted claims

after assessing the intrinsic evidence, it may look to additional extrinsic evidence to help resolve any lack of clarity").

One-SD's proposed construction of "connected to said hub" is further flawed because it either adds redundant verbiage or adds unsupported features to the claim term. If the word "linked" has no independent meaning beyond "joined"—and One-SD does not suggest that it does—then One-SD's proposed construction seeks to improperly insert additional, but entirely superfluous, language to the disputed claim term. *See, e.g., Chicago Bd. Options Exch., Inc. v. Int'l Securities Exch., LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012) (there is a "general presumption that different terms have different meanings"); *CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings"). However, if the term "linked" has a meaning beyond that of "joined," then One-SD proposes a construction that improperly expands the disputed claim language without *any* intrinsic evidence to support such an expansion. *See Phillips*, 415 F.3d at 1312-17; *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 996 (Fed. Cir. 2006) ("[o]ur primary focus in determining the ordinary and customary meaning of a claim limitation is to consider the intrinsic evidence of record"). In either case, One-SD's proposed construction should be rejected.

### C. Terms Related to the Diaphragm to Prevent Blood Spillage

#### 1. "Flexible, Resilient Diaphragm" (claims 22 )

In its opening brief, BD proposed that the Court construe the term "flexible, resilient diaphragm" as "a flexible, resilient seal that prevents the flow of liquid out of the catheter hub." However, since BD's briefing, the PTO has issued an initial construction of this term as "a thin sheet of material forming a partition which is capable of bending or being penetrated by a needle

easily without breaking and able to spring back into shape after being penetrated." (Halijan Decl. Ex. 1 at 11.) BD maintains its position on the proper construction of the term, but acknowledges that the PTO's construction is now relevant intrinsic evidence on the meaning of the term.

**2. "Attached Between Said Body and a Proximal End of Said Hub Proximal To Said Side Access Port" (claim 22)**

One-SD's proposed construction fails to construe the term "between" in this limitation. Under One-SD's proposed construction, the diaphragm could be located anywhere in the catheter even though the claim expressly states that it is attached at a particular place between the catheter hub and the needle attachment body. For this reason alone, One-SD's construction should be rejected. *See, e.g.*, *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 781 (Fed. Cir. 2010) ("we construe claims with an eye toward giving effect to all of their terms"); *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1444 (Fed. Cir. 1997) (rejecting the patentee's claim construction because it "would render the contested terms surplusage"); *Tex. Instruments Inc. v. ITC*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (rejecting a construction that "would render the disputed claim language mere surplusage").

In contrast, BD's construction of claim 22 requires "a flexible resilient diaphragm attached *between* said body and a proximal end of said hub." (emphasis added). BD proposes that the term be construed as "a seal that is held in place in a space that separates the needle attachment body and a proximal end of the catheter hub." Although the PTO offered a broader construction with respect to the term "between" than BD now proposes (construing the term as "at, into, or across the space separating (two objects or regions)"), the Court should adopt BD's proposed construction. (*See* Halijan Decl. Ex. 1 at 12-13.) In an IPR proceeding, the PTO construes claims under the "broadest reasonable construction in light of the specification of the

patent in which it appears" standard. 37 C.F.R. § 42.100(b). In contrast, district courts construe terms according to their "ordinary and customary meaning" as described in the claims, specification, prosecution history, and when needed, extrinsic evidence. *Phillips*, 415 F.3d at 1312-18. Accordingly, BD's proposed construction for the term "between" is a proper approach for this Court's claim construction proceeding and should be adopted, notwithstanding the broader construction by the PTO.

One-SD's attempt to construe "attached" as "directly or indirectly attached" should also be rejected. One-SD does not explain what "indirectly attached" means. Despite its claim differentiation argument, what One-SD is really attempting to accomplish is to insert verbiage into the claim construction process that does not aid in understanding the claimed invention but instead creates additional confusion, *e.g.*, the meaning of "indirectly." *See Harris Corp. v. IXYS Corp.*, 114 F.3d 1149, 1152 (Fed. Cir. 1997).

**3. "The Flow Of A Liquid Through Said Hub Lumen Past Said Side Access Port and Through the Proximal End of Said Hub External To Said Introducer Needle Cannula" (claim 22)**

One-SD's construction of this phrase should be rejected because it introduces a feature not described in the '914 patent. One-SD proposes that the claim term means that "the diaphragm prevents liquid that is flowing through the hub passageway and past the side access port from exiting the proximal end of the hub, except through the needle passageway." (Br. at 10.) One-SD's proposed construction introduces a "hub passageway," which is a new term that is not described in the claims or in the specification. Instead, claims 22 and 31 of the '914 patent describe a "hub lumen" and a "catheter passageway." *See* '914 patent, col. 11:26-30, col. 12:7-14, col. 12:31. Thus, One-SD's proposed construction confuses the hub lumen and the catheter passageway and improperly introduces a new term, "hub passageway," for construction and should accordingly be rejected.

**4. "Flexible, Resilient Diaphragm … For Preventing the Flow of a Liquid" (claim 31)**

One-SD proposes that the Court construe this text from claim 31:

> flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub[.]

One-SD proposes that this term be construed as: "a pliable membrane, capable of being penetrated by a needle and returning to its shape after deformation, which is indirectly or directly attached to the hub to partition the hub passageway to prevent liquid from exiting the proximal end of the hub except through the needle passageway, if a needle is penetrating the membrane." One-SD's proposed construction of this text fails, however, to address a key limitation of claim 31. Specifically, claim 31(but not claim 22) requires that the diaphragm seal the hub in a "liquid tight manner." One-SD's proposed construction effectively reads this phrase out of the claim by offering a construction for claim 31 that is substantially similar to claim 22 without reflecting this distinction. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950-52 (Fed. Cir. 2006) (rejecting a proposed claim construction because it would "read limitations…out of the claim. Not only would that be contrary to the principle that claim language should not [be] treated as meaningless, but it would be contrary to the specification…."); *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 546 (Fed. Cir. 1994) ("All limitations in a claim must be considered meaningful."). Conversely, BD's construction of claim 31 explains that the diaphragm is attached to "prevent the flow of all liquid past the seal" and is consistent with the specification. *See* '914 patent, col. 4:24-30.

### D. Terms Related to the Fenestrations on the Needle

#### 1. "Central Portion" (claims 22 and 31)

One-SD's proposed construction eliminates the phrase "central potion" from claims 22 and 31. One-SD argues that the term "central portion" allows the fenestrations on the needle of the '914 patent to be located *anywhere* "between the ends of the needle." (Br. at 13.) One-SD's proposal is apparently meant to distinguish the claimed fenestrations, which the claims require to be located on a "central portion" of the needle, from the holes at the end of the needle. However, the patent itself distinguishes the "fenestration" from the holes at the end of the needle. One-SD does not contest, and cannot contest, that the needle on which the fenestrations are located is "cannulated." Indeed, both claim terms discuss the "cannula" of the introducer needle. A cannulated needle is a hollow needle with holes on the ends. Thus, a "fenestration"—absent any further language about its location—must be located along the length of the needle because a cannulated needle already has holes at its ends.

However, claims 22 and 31 do not just require a "fenestration," but rather require a "fenestration" located "on a central portion" of the *cannulated* needle. Thus, the term "central portion" gives further guidance as to the fenestration's location beyond just being between the ends of the cannulated needle. For all of the reasons outlined in BD's opening brief, the limitation "on a central portion" must mean what it suggests—closer to the center than the ends of the needle.

#### 2. "Which Communicates with a Cannula of Said Introducer Needle and … With Said Hub Lumen" (claims 22 and 31)

One-SD's overbroad construction of this second part of the fenestration limitation covers fenestrations that would allow blood into the catheter passageway *outside* the hub. Specifically, One-SD proposes a construction that "when the needle is in the operative position, [the

fenestration] permits liquid flow from the needle passageway into the catheter passageway, whether or not the fenestration is disposed within the hub passageway when the needle is in the operative position." However, the claim language requires that the fenestration communicate with the *hub lumen*, not with the catheter passageway. Furthermore, One-SD's arguments improperly focus on an "unbroken passage of liquid from the needle." But the claim language requires that *the fenestration* itself—not a liquid—communicates with the hub lumen. The fenestration (*i.e.*, an opening in the needle) is a structure, and thus can only communicate with the hub when the fenestration is aligned with the hub in the operative position. *See, e.g., K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.").

One-SD attempts to distract the Court from its flawed constructions by relying on claim differentiation, arguing that dependent claim 27 adds the limitation "wherein said at least one fenestration is disposed within said hub lumen when said introducer needle is disposed in said operative position." (Br. at 13.) This argument fails for two reasons.

*First*, claim differentiation is not dispositive on this issue, particularly where the limitation in question was a point of distinction for overcoming the prior art during prosecution, and One-SD's proposed construction would improperly recapture claim breadth that was surrendered. *See Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1359 (Fed. Cir. 2012) (*en banc*) ("As we have held, claim differentiation is 'not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history."' (quoting *Seachange Int'l, Inc. v. C–COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005))); *see also Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991) ("Claim differentiation is a guide, not a rigid rule.") (quotation omitted); *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651

F.3d 1318, 1337 (Fed. Cir. 2011) ("the doctrine of claim differentiation is not a conclusive basis for construing claims"). As discussed in BD's opening brief, during prosecution of the application that issued as the '914 patent, the Examiner rejected the pending claims in view of the prior art, to which the Applicant responded by arguing that the claimed fenestrations were required to be "disposed within the catheter hub." When arguing the patentability of claim 22, the Applicant expressly adopted this reasoning. (Halijan Decl. Ex. 4.) One-SD's proposed construction thus improperly seeks to recapture what the patentee previously disclaimed. *See Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." (citing *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-21 (1940); *Crawford v. Heysinger*, 123 U.S. 589, 602-04 (1887); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880))).

*Second*, One-SD's proposed construction for claim 22 has no support in the specification. Specifically, the specification requires a space for blood flow between the catheter hub and the needle, but has no suggestion of such a feature with respect to the catheter tube itself and the needle. *See* '914 patent, col. 5: 34-40. Likewise, the specification states that the catheter hub (but not the catheter tube) is preferably formed of clear plastic "so that a blood flash back can be readily observed therein upon successful penetration of the lumen of a blood vessel by the needle tip 28." '914 patent, col. 5:55-58. Thus, the only mechanism described or enabled for displaying "flash back" is through the use of fenestrations along the central portion of a needle that are aligned with the clear hub.

In contrast with One-SD's arguments, the specification explains that the fenestrations are "properly positioned" when blood can flow from the needle cannula through the fenestrations and into the hub. '914 patent, col. 5:34-40; *see also* col. 8:37-41. Blood flows through the fenestrations and into the hub because the diameter of the catheter hub is greater than the diameter of the needle, creating a space for blood flow. *Id.* at col. 5:34-40. Because the catheter hub is preferably "formed of a rigid clear plastic," this blood flow into the hub is observable to the clinician and constitutes the "flash back" described as an objective of the patent. *Id*. at col. 5:55-58.

## IV. CONCLUSION

For the foregoing reasons, BD respectfully requests that the Court adopt its proposed constructions of the claims of the '914 patent.

October 14, 2013

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing document was forwarded via the Court's electronic filing system to Joel T. Beres, Esq., James R. Michels, Esq., William C. Ferrell, Jr., Esq., Melissa Hunter Smith, Esq., and Kevin P. Hartley, Esq., of Stites & Harbison, PLLC, 401 Commerce Street, Suite 800, Nashville, TN 37219-2376, this 14th day of October, 2013.

/s Douglas F. Halijan